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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,147	09/27/2001	Leonard G. Presta	GENENT.33CPC4C	4067
20995	7590	07/23/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			UNGAR, SUSAN NMN	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1642	

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,147

Applicant(s)

PRESTA ET AL.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-7, 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 4-7, 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

1. The Amendment filed May 13, 2004 in response to the Office Action of January 15, 2004 is acknowledged and has been entered. Previously pending claims 8-14 have been cancelled, claims 1 and 23 have been amended. Claims 1, 4-7, 23 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

Claim Rejections - 35 USC 112

4. Claims 1, 4-7, 23 remain rejected under 35 USC 112 for the reasons previously set forth in the paper mailed January 15, 2004, Section 9, pages 5-11.

Applicant argues that (a) since the claims are now directed to use of antibodies specifically binding the full-length trkC receptor of SEQ ID NO:6, without the associated signal sequence, any issues concerning the potentially different biological activities of the various splice forms no longer apply, (b) as to why trkC antagonists are proposed for the inhibition of aberrant neuron sprouting in epilepsy, no explanation is legally required to meet the enablement requirement, (c) it is incorrect for the Examiner to dismiss the teaching of Kim et al just because the authors, in the customary style of scientific publications, suggest that trkC may have a critical role in the pathogenesis of epilepsy. The important part of the statement referred to is that Kim et al suggested a critical pathogenic role for trkC in epilepsy, (d) all the assertions concerning the potential issues related to clearance, stability, etc are entirely irrelevant to the assessment of enablement since the patent statute does not require that applicants provide details of an invention in a commercially available form. Consideration of such issues is within the competence of the FDA and not the patent office.

The arguments have been considered but have not been found persuasive because (a') although the antagonistic antibodies are required to specifically bind to a sequence within amino acid residues 32 and 839 of SEQ ID No: 6, the claims are clearly not limited to contacting SEQ ID No:6 expressed in neuron cells. Claim 1 as currently constituted is specifically drawn to contacting "a human trkC receptor of SEQ ID No: 6 expressed in neuron cells". The claim is not drawn to contacting SEQ ID No: 6, but rather is drawn to contacting a (emphasis added) human trkC receptor of SEQ ID No: 6. Given the definition of a trkC in the specification it is clear that the claims as currently constituted are drawn to not only the full-length receptor but also its truncated and variant forms such as those arising by alternate splicing and/or insertion and naturally occurring allelic variants of SEQ ID NO:6. The claim still reads on contacting the various splice forms since it would be expected that those splice forms would comprise at least some of the sequences within amino acid residues 32 and 839 and 839 of SEQ ID NO:6 and issues concerning the potentially different biological activities of the various splice forms certainly do apply, further, as previously set forth, no nexus has been established between any particular trkC of SEQ ID NO:6 and aberrant sprouting in any disease, (b') contrary to applicants arguments, given that the invention is an undeveloped art, given the statements of Kim et al, of record, wherein eight years post-filing, the role of trkC in epilepsy was still being hypothesized, it is clear that in the absence of objective evidence demonstrating the role of antagonists to trkC in the inhibition of aberrant neuron sprouting, *in vivo*, no one of skill would believe it more likely than not that the invention would function as claimed based only on a single comment in the specification. In particular, it is noted that MPEP 2164.03 teaches that "the amount of guidance or direction needed to enable the

invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order to be enabling.” Given the unpredictability of using the invention for the reasons of record, given that the invention is an undeveloped art, more is required than a simple mention that “antagonists of TrkC receptor polypeptides are believed to be useful for treating aberrant sprouting in epilepsy”, (c’) contrary to applicants arguments, Examiner in no way dismisses the teachings of Kim et al. Although applicant interprets the teaching as a customary style of scientific publications and states that the important part of the statement is drawn to the critical pathogenic role for trkC in epilepsy, it appears that it is applicant and not Examiner who is dismissing the teachings of Kim et al. Kim et al do not state that trkC has a critical pathogenic role but rather states that trkC may have that role and for the reasons of record it cannot be predicted that the invention will function as claimed, (d’) although the Office does not require that applicants provide details of an invention in a commercially available form, the Office does require that applicants provide details of an invention in a form that would teach how to make and use the claimed invention with a reasonable expectation of success. Given the single statement drawn to a belief that antagonists of trkC receptor can be used for

treating aberrant sprouting in epilepsy, given the lack of teaching as to which form, if any, of trkC is involved in aberrant sprouting, given the teaching of Kim et al, no one of ordinary skill in the art would believe it more likely than not that the invention would function as claimed. Further, contrary to applicants arguments for the reasons set forth above, more than the statement drawn to applicant's belief that antagonists of trkC are useful for treating aberrant sprouting in epilepsy is required in order to meet the enablement requirements of the patent statute's. A teaching of how to make and use the claimed invention in the specification as originally filed is required for the enablement of the claims under the patent statutes. Applicant does not meet the requirements of 35 USC 112, first paragraph for the reasons of record.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

It is noted that applicant has not addressed the issues raised drawn to the overexpression of non-productive trkC in adults compared with productive trkC and the effects of the nonproductive trkC on the method as claimed.

5. Claims 1, 4-7, 23 remain rejected under 35 USC 112 for the reasons previously set forth in the paper mailed January 15, 2004, Section 10, pages 11-15.

Applicant argues that (a) the findings in Lilly and Enzo are drawn to DNA-related inventions and therefore the cited cases do not constitute applicable caselaw since there is nothing that indicates that the CAFC intended the rules established by these cases to be generally applicable, regardless of the nature of the invention, (b) other than citing unrelated caselaw the Examiner has not advanced any evidence or solid scientific arguments why a person of ordinary skill in the art

would not have reasonably accepted that applicants were in possession of the claimed invention at the priority date of this application.

The arguments have been considered but have not been found persuasive because (a') the findings in the two cited cases are clearly relevant to the instant claims since the instant claims are drawn to naming a type of material generally known to exist in the absence of knowledge as to what that material consists of. There has been no nexus made between any trkC sequence and aberrant neuron sprouting, no nexus made between trkC and epilepsy, there is no description of the structure of the population of cells associated with aberrant neuron sprouting and without that description the specification cannot adequately describe a method of inhibiting aberrant neuron sprouting since no one can know what population of cells, or which trkC receptor to treat. Further although the specification mentions antagonists of trkC the specification fails to describe a representative number of such species and the specification does not provide an adequate written description of the claimed invention that is required to practice this invention, (b') for the reasons of record applicant has not provided an adequate written description of the claimed invention required to practice this invention.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

6. No claims allowed.
7. All other objections and rejections recited in the paper mailed January 15, 2004 are hereby withdrawn.
8. **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF

Art Unit: 1642

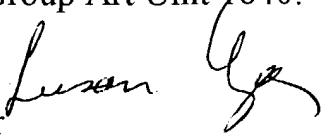
THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0837. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

Susan Ungar 
Primary Patent Examiner
July 16, 2004